



ATTORNEY'S DOCKET NUMBER: 0492611-0375 (MIT 8802)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kamm, *et al.* Examiner:
Serial No.: 09/815,528 Art Unit:
Filed: March 23, 2001
For: METHOD AND APPARATUS FOR STIMULATING ANGIOGENESIS AND
WOUND HEALING BY USE OF EXTERNAL COMPRESSION

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

Sir:

**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants request consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

(Select A, B, C or D below)

- A. [X] This Information Disclosure Statement has been filed:
1. [X] within three months of the filing date of the above identified U.S. Patent application other than a continued prosecution application under § 1.53(d);
 2. [] within three months of the filing date of the entry of the National Stage, as set forth in 37 C.F.R. §1.491, in an International application;
 3. [] before the mailing date of the first Office Action on the merits in the above-identified application; or
 4. [] before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

No fee or certification is required.

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B. [] This Information Disclosure Statement has been filed more than three months after the filing date of the present application and after the mailing date of the first Office Action, but before the mailing date of any of a final action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application, and:

(check 1 or 2 below)

1. [] The fee of \$180 as set forth in 37 C.F.R. §1.17(p) is enclosed, OR
2. [] The Applicants hereby certify, as specified in 37 C.F.R. §1.97(e), that

(check a or b below)

- a. [] each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement; or
- b. [] no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Statement.

C. [] This Information Disclosure Statement has been filed after the mailing date of either a Final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311 and on or before payment of the Issue Fee.

1. The Applicants hereby certify, as specified in 37 C.F.R. §1.97(e), that:
 - a. [] each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement; or
 - b. [] no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a

counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Statement; AND

2. The Petition Fee of \$180 as set forth in 37 C.F.R. §1.17(p) is enclosed.
- D. [] This Information Disclosure Statement does not comply with any of the provisions set forth above, or is being submitted after the payment of the issue fee; however, Applicants respectfully request that the Statement be placed in the above-referenced file.

PART II - 37 CFR § 1.98 Content of Information Disclosure Statement:

- [] A. Applicants hereby make of record in the above-identified application all patents, publications, applications or other information submitted for consideration by the Office listed on the attached form PTO-1449 (modified). The order of presentation of the patents, publications, applications or other information should not be construed as an indication of the importance. Applicants have provided a legible copy of:
- each U.S. patent application publication;
 - each U.S. foreign patent;
 - each publication or that portion which caused it to be listed;
 - each pending U.S. application (including the application specification including the claims and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion); and
 - other information or that portion which caused it to be listed.

For each patent, publication, or other information listed that is not in the English language, the following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449 (modified):

Alternatively, if a written English-language translation of a non-English-language document, or portion thereof, if within the possession, or control of, or is readily available to any individual designated in § 1.56(c), a copy of the translation is provided herein as identified:

[] B. The Applicants hereby make the following additional information of record in the above-identified application:

PART IV: Remarks

A copy of each of the above-identified U.S. and foreign patent(s), publication(s), application(s) or other information submitted is enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s), publication(s), application(s), or other information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, Applicants make no representation that a search has been performed, of the extent of any search performed, or that more material information may not exist.

By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited materials. An early and favorable action is hereby requested.

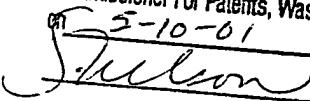
Respectfully submitted,



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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner For Patents, Washington, D.C. 20231

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Form PTO-1440
(REV. 8-83)

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U.S. Department of Commerce
Patent and Trademark OfficeAtty. Docket:
0492611-0375In re Application No.
09/815,528RECEIVED
Information Disclosure Statement
(Use several sheets if necessary)Filing Date:
March 23, 2001Group:
JUL 01 2004
TECHNOLOGY CENTER 2000**U.S. PATENT DOCUMENTS**

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	3,707,960	Freed	January 2, 1973	128	2.06
	3,783,859	Sauer, et al.	January 8, 1974	128	24
	4,527,549	Gabbay	July 9, 1985	128	1
	4,552,127	Schiff	November 12, 1985	128	1
	4,692,148	Kantrowitz, et al.	September 8, 1987	604	96
	4,966,849	Vallee, et al.	October 30, 1990	435	199
	5,218,954	van Bemmelen	June 15, 1993	128	24
	5,407,418	Szpur	April 18, 1995	601	104
	5,486,457	Butler, et al.	January 23, 1996	435	7.2
	5,496,262	Johnson, Jr., et al.	March 5, 1996	601	152
	5,554,103	Zheng, et al.	September 10, 1996	601	152
	5,997,540	Zheng, et al.	December 7, 1999	606	64
	6,076,013	Brennan, et al.	June 13, 2000	607	2
	6,078,235	Schebitz, et al.	June 20, 2000	335	220

U.S. PATENT APPLICATIONS

Examiner's Initials:	Serial Number:	Applicant:	Filing Date:	Group:	Art Unit:

FOREIGN PATENT DOCUMENTS

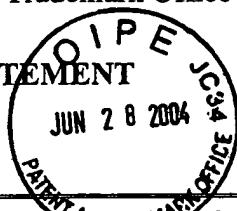
Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No
	WO 00/40740	PCT	13 July 2000		
	WO 95/01770	PCT	19 January 1995		

OTHER DOCUMENTS

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	Amsterdam, et al., "Clinical Assessment of External Pressure Circulatory Assistance in Acute Myocardial Infarction", <i>Am. J. Cardiol.</i> , 45: 349, 1990.

FORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

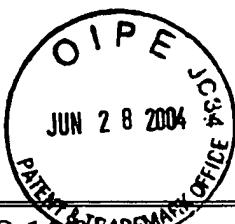


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	Kamiya, et al., "Adaptive Regulation of Wall Shear Stress Optimizing Vascular Tree Function", <i>Bull. Math. Biol.</i> 46: 127-137, 1984.
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	Lawson, et al., "Efficacy of Enhanced External Counterpulsation in the Treatment of Angina Pectoris", <i>American Journal of Cardiology</i> , 70(9): 859-862, 1992.
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Form PTO-1449 (REV. 8-83)		U.S. Department of Commerce Patent and Trademark Office	Atty. Docket: 0492611-0375	In re Application No. 09/815,528
INFORMATION DISCLOSURE STATEMENT <i>(Use several sheets if necessary)</i>		Applicant: Kamm, et al.		
		Filing Date: March 23, 2001	Group:	
<p>Endothelium" <i>Journal of Clinical Investigation</i>, 92: 2013-2021, 1993.</p> <p>Mason, "The Ins and Outs of Fibroblast Growth Factors" <i>Cell</i>, 78(4): 547-552, 1994.</p> <p>Mitsumata, et al., "Fluid Shear Stress Stimulates Platelet-Derived Growth Factor Expression in Endothelial Cells" <i>American Journal of Physiology</i>, 265(1): H3-H8, 1993.</p> <p>Parmley, et al., "Hemodynamic Effects of Noninvasive Systolic Unloading (Nitroprusside) and Diastolic Augmentation (External Counterpulsation) in Patients with Acute Myocardial Infarction", <i>Am. J. Cardiol.</i> 33: 819-825, 1974.</p> <p>Pedley, et al., "Energy Losses and Pressure Drop in Models of Human Airways", <i>Respiration Physiology</i>, 9:371-386, 1970.</p> <p>Soran, et al., "Enhanced External Counterpulsation in the Management of Patients with Cardiovascular Disease", <i>Clin. Cardiol.</i> 22: 173-178, 1999.</p> <p>Soroff, et al., "External Counterpulsation, Management of Cardiogenic Shock After Myocardial Infarction", <i>J. Am. Med. Assn.</i> 229: 1441-1450, 1974.</p> <p>Stettler, et al., "Theoretical Analysis of Arterial Hemodynamics Including the Influence of Bifurcations" <i>Annals of Biomedical Engineering</i>, 9: 145-164, 1981.</p> <p>Suga, et al., "Instantaneous Pressure-Volume Relationships and Their Ratio in the Excised, Supported Canine Left Ventricle", <i>Circulation Research</i>, 35: 1974.</p> <p>Suga, et al., "Determinants of Instantaneous Pressure in Canine Left Ventricle: Time and Volume Specification", <i>Circ. Res.</i> 46: 256-263, 1980.</p> <p>Sumpio, "Hemodynamic Forces and the Biology of the Endothelium: Signal Transduction Pathways in Endothelial Cells Subjected to Physical Forces in Vitro" <i>Journal of Vascular Surgery</i>, 13(5): 744-746, 1991.</p> <p>Suresh, et al., "Maximizing the Hemodynamic Benefit of Enhanced External Counterpulsation", <i>Clinical Cardiology</i>, 21(9): 649-653, 1998.</p> <p>Young, et al., "Flow Characteristics in Models of Arterial Stenoses". <i>J. Biomechanics</i>, 6: 547-559, 1973.</p> <p>Zheng, et al., Sequential External Counterpulsation (SECP) in China", <i>Transactions of the American Society of Artificial Internal Organs</i>, 29: 599-603, 1983.</p>				